REMARKS

Reconsideration is respectfully requested. Claims 1-12 were present in the application. Claims 1, 4-9, 11 and 12 are amended. Claim 3 is canceled. New claims 13-16 are added.

Responsive to the Office Action, the applicant amends claims 1 and 4 to 9, and incorporates some limitations in original claims 1 and 4. After the amendments, the applicant believes that the pharmaceutical composition claimed in claim 1 cannot be anticipated by the citation United States Patent No. 5,753,706 (Hsu).

The applicant submits that the present application relates to ferric citrate having a fixed molecular structure and a definite mean number of water molecules, which was prepared according to the present invention for the first time. According to the present invention, ferric citrate was prepared with a fixed molecular structure and a definite amount of water, wherein the molecular structure has 1:1 molar ratio of iron ion(III) and citrate.

With reference to Table I in the specification, the data show that the molar ratios of iron ion(III) and citrate from the commercial sources are varied. Because the molar ratios of iron ion(III) and citrate of the products from different commercial sources are various and unfixed, the exact structures of ferric citrate products from the commercial sources are difficult to

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define. (see the "Difference" in Table 1). In Table I, ferric citrate products from the commercially available sources were assayed by the ferric titration and the citrate HPLC method. Ferric citrate products from different commercial sources were calculated by the ferric assay based on an assumed molar ratio of iron ion(III): citrate = 1: 1.(citrate/iron = 189.11/55.85= 3.39, molecular weights of citrate and iron are 189.11 and 55.85, respectively). The ferric citrate products from different commercial sources were also calculated by the addition of the ferric assay result and the citrate HPLC method and resulted values of (HPLC + titration). Each value of "Difference (%)" results from the comparison of the value of (HPLC + titration) of ferric citrate and the value of the ferric titration of ferric citrate. The greater the "Difference (%)" is, the more the variety of the molecular structures of ferric citrate is.

With reference to Table II in the specification, the values of "Difference" from four lots are small. The results indicate that each ferric citrate molecule in four lots is fixed in molecular structure.

Further, ferric citrate products from different lots was dried and then accurately weighed to calculate the amount of water contained in the ferric citrate. Surprisingly, the applicant found that each ferric citrate molecule obtained from different lots in the present invention also contains a definite

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mean number of water molecules. For instance, as described in lines 12 to 14 on page 10 of the specification, three and a half water molecules were determined from the assay results of ferric citrate in the four lots. Therefore, the ferric citrate molecules obtained according to the present invention are uniform with increased acceptance and stability for the use in the manufacture of a pharmaceutical composition. Also, the ferric citrate obtained from the present invention would cause a significant decrease in uncertainties when being used for treatment of patients.

Even though the citation disclosed a pharmaceutical composition comprising ferric citrate and a pharmaceutically acceptable carrier, the state of the art at the time this application was filed neither taught nor suggested the ferric citrate according to the present invention having a fixed molecular structure and a definite mean number of water molecules. Therefore, the claimed invention is not anticipated.

To further differentiate the present claims from the state of the art, the features of the superior fixedness and the definite amount of water in view of the data given in the originally filed specification are introduced into Claim 1 for additional clarification.

I. Response to the Examiner's Rejection to Claim 3 under 37 CFR 1.75(c)

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Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The Examiner asserted that claim 3 merely recites the intended function of the composition of claim 1 and does not provide for any further physical or otherwise material limitation.

To overcome the Examiner's objection, the applicant has canceled claim 3 and rewritten it in form as shown in claim 16 (newly added). It is respectfully submitted that new claim 16 is allowable.

II. Response to the Examiner's Rejection of Claims 1 10 under 35 U.S.C. §112, second paragraph

Claims 1-10 are rejected under 35 U.S.C. §112, second paragraph, as being deemed indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner asserted that in claims 1 and 4, the metes and bounds of the expression `pharmaceutical grade ferric citrate' are unclear. In particular, such an expression allegedly fails to make clear what difference, if any, there is between the applicant's ferric citrate and that ferric citrate normally employed in pharmaceutical preparations.

In currently amended independent claims 1 and 4, the applicant has decided to cancel the expression "pharmaceutical grade" to clarify the claims and to overcome the rejection. As

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described in line 5 on page 2 of the specification, the applicant has also amended the independent claim 1 by specifying ferric citrate has a fixed molecular structure and a definite mean number of water molecules.

III. Response to the Examiner's Rejection of Claims 1 3 under 35 U.S.C. §102(b)

Claims 1 3 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Hsu (U.S. Patent No. 5,753,706, cited by the applicant) who teaches pharmaceutical compositions comprising ferric citrate and a pharmaceutically acceptable carrier (col. 2, Lines 49 and 55-65 and col. 3, lines 40-45).

Applicant respectfully traverses. As illustrated in line 6 on page 2 and in the Example 4 in the specification, the ferric citrate obtained according to the present invention has a fixed molecular structure and a definite number of water molecules. The characteristics of a fixed molecular structure and a definite amount of water are very important for pharmaceutical purposes, because a practitioner can provide a precise dosage of ferric citrate by an accurate calculation and anticipate a probable efficacy when using the ferric citrate according to the present invention. Also, the ferric citrate obtained from the present invention would cause a significant decrease in uncertainties when being used for treatment of patients.

However, a ferric citrate product that is commercially available contains various molar ratios of iron ion and citrate

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and various amounts of water. A skilled practitioner finds it both difficult to provide an accurate dose of ferric citrate for pharmaceutical purposes and difficult to expect the efficacy when using the commercially available ferric citrate products.

Even though the citation disclosed a pharmaceutical composition comprising ferric citrate and a pharmaceutically acceptable carrier, the state of the art at the time this application was filed neither taught nor suggested the ferric citrate according to the present invention having a fixed molecular structure and a definite mean number of water molecules. Therefore, the there was no way to anticipate the present invention.

III. Response to the Examiner's Rejection of Claim 1-3, 11 and 12 under 35 U.S.C. §103(a)

Claims 1-3, 11 and 12 are rejected under 35 U.S.C. §103 (a) as being unpatentable over Hsu (U.S. Patent No. 5,753,706), as above, in light of applicant's acknowledgments at page 1, line 21 page 2, line 3 of the present specification. Applicant respectfully traverses.

The Examiner asserted that Hsu further teaches the incorporation of the ferric citrate into a food composition (col. 3, line 62).

The present application relates to a novel disclosure concerning a pharmaceutical composition comprising ferric

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citrate that was prepared with a fixed molecular structure and a definite mean number of water molecules.

Since Hsu did not disclose a ferric citrate molecule having a fixed molecular structure and a definite mean number of water molecules, no evidence indicates that an ordinary person skilled in the art could devise the pharmaceutical composition comprising ferric citrate of currently amended claim 1, which has a fixed molecular structure and a definite number of water molecules (e.g., 3.5 water molecules).

Accordingly, the subject matter of currently amended claims 1, 2, 11 and 12 was arrived at based on knowledge that Hsu's patent neither teaches nor suggests. Currently amended claims 1 2, 11 and 12 are not obvious to a person skilled in the art in light of Hsu's patent.

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After the foregoing amendments and remarks, the applicant respectfully submits that the present application is patentable in view of the cited prior art. Thus, favorable reconsideration is courteously solicited.

The Examiner is asked to contact applicant's attorney at 503-224-0115 if there are any questions.

Respectfully submitted,

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